

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

**ANSWER OF BRISTOL-MYERS SQUIBB COMPANY, ONCOLOGY THERAPEUTICS
NETWORK CORPORATION AND APOTHECON, INC. TO PLAINTIFFS' AMENDED
MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

Defendants Bristol-Myers Squibb Company ("Bristol-Myers"), Oncology Therapeutics Network Corporation ("OTN"), and Apothecon, Inc. ("Apothecon") (Bristol-Myers, OTN and Apothecon are collectively referred to herein as the "BMS Group"),¹ respond to Plaintiffs' Amended Master Consolidated Class Action Complaint (the "AMCC"), served via Verilaw on January 22, 2004, as follows:

Preliminary Statement

The AMCC improperly refers to Bristol-Myers, OTN, and Apothecon, other Defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Bristol-Myers, OTN and/or Apothecon. This is insufficient to apprise BMS Group (let

¹ In this Answer, Bristol-Myers, OTN and Apothecon follow the convention of the AMCC by referring to themselves collectively as the "BMS Group." By following the AMCC in this manner, none of these Defendants concedes or admits that it is properly defined as a "Group" for any other purpose.

alone each separate entity) of the allegations asserted against it. BMS Group has nevertheless attempted to respond to Plaintiffs' allegations to the extent possible.

To the extent the AMCC's allegations refer to the knowledge, conduct or actions of other persons or entities, BMS Group is generally without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that it is answering Plaintiffs' allegations solely on behalf of itself, even when Plaintiffs' allegations refer to alleged conduct by BMS Group and other persons or entities.

The AMCC also contains purported quotations from a number of sources, many of which are unidentified. In answering allegations consisting of quotations, a failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or a reference to the full document shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

BMS Group denies each and every allegation contained in the AMCC, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any averment or in the AMCC as a whole. Moreover, BMS Group specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered paragraphs in the AMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

Specific Responses

1. BMS Group admits that Plaintiffs seek to bring this action as alleged in Paragraph 1 of the AMCC. BMS Group denies that Plaintiffs are entitled to maintain this action in the manner alleged.

2. BMS Group denies the allegations in Paragraph 2 of the AMCC.

3. BMS Group denies the allegations in Paragraph 3 of the AMCC, except admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications and that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP.

4. BMS Group denies the allegations in Paragraph 4 of the AMCC, except admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP, and further admits that Medicare Part B medicines are generally, but not always, administered in a healthcare provider's office.

5. BMS Group denies the allegations in Paragraph 5 of the AMCC, except admits that AWP (often less a negotiated percentage discount) is sometimes used as a basis for reimbursement in transactions outside the Medicare Part B context.

6. BMS Group denies the allegations in Paragraph 6 of the AMCC, except admits that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the AMCC, but BMS Group further denies that Plaintiffs are entitled to maintain this action in the manner alleged.

7. BMS Group denies the allegations in Paragraph 7 of the AMCC.

8. BMS Group denies the allegations in Paragraph 8 of the AMCC, except admits that it participates in the Together Rx Card Program which commenced in 2002 and allows eligible persons to enjoy discounts on covered medicines.

9-10. BMS Group denies the allegations in Paragraphs 9 through 10 of the AMCC.

11. BMS Group admits that Plaintiffs have filed attachments to the AMCC as alleged in Paragraph 11 of the AMCC. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in the attachments. BMS Group denies the remaining allegations in Paragraph 11 of the AMCC.

12. The Court dismissed Count I in its Order dated February 25, 2004. Accordingly, BMS Group does not respond to Paragraph 12 of the AMCC. To the extent a response is required, BMS Group denies the allegations in Paragraph 12 and Count I of the AMCC.

13-21. BMS Group denies the existence of, or its participation in, any "enterprise," "scheme" or "conspiracy" or wrongdoing of any kind as alleged in Paragraphs 13 through 21 of the AMCC. BMS Group admits that Plaintiffs purport to bring this action as a class action and that Plaintiffs seek relief under Counts II through X as alleged in Paragraphs 13 through 21 of the AMCC. BMS Group denies that this action can be maintained in the manner alleged, and further denies that Plaintiffs are entitled to relief under Counts II through X of the AMCC.

22-24. The allegations in Paragraphs 22 through 24 of the AMCC state legal conclusions to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraphs 22 through 24 of the AMCC.

25. BMS Group admits the allegations in Paragraph 25 of the AMCC.

26-31. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 26 through 31 of the AMCC.

32-36. BMS Group admits that Plaintiffs VPIRG, WCA, StateWide, CANY and CCJ purport to bring this action as alleged in Paragraphs 32 through 36 of the AMCC, but BMS Group denies that these Plaintiffs have standing to bring the alleged action. BMS Group is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraphs 32 through 36 of the AMCC.

36(a)–(c). BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 36(a) through 36(c) of the AMCC.

37-38. BMS Group denies the allegations in Paragraphs 37 through 38 of the AMCC that pertain to it. BMS Group denies the existence of, or its participation in, any “conspiracy” as alleged in Paragraph 38 of the AMCC. To the extent the allegations in Paragraphs 37 through 38 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations.

39-70. The allegations in Paragraphs 39 through 70 of the AMCC are directed to other defendants and require no response from BMS Group. To the extent the allegations in Paragraphs 39 through 70 of the AMCC are deemed to include allegations against BMS Group, they are denied.

71. Bristol-Myers admits that it is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers admits it has offices, facilities and businesses both inside and outside the United States and that it is involved in the manufacturing, marketing and sale of pharmaceuticals and health care products. Bristol-Myers denies the remaining allegations in Paragraph 71 of the AMCC and refers to its SEC filings for its financial information.

72. OTN admits that it is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, California. OTN admits

it has been a wholly-owned subsidiary of Bristol-Myers since 1996. OTN denies the remaining allegations in Paragraph 72 of the AMCC.

73. Bristol-Myers and OTN deny the allegations in Paragraph 73 of the AMCC, except OTN admits that it is a health care services and distribution firm that sells, among other things, Bristol-Myers' infusion oncology drugs and related products to office-based oncology practices in the United States; OTN admits that at the time of its acquisition by Bristol-Myers, it was a leading distributor of chemotherapeutic drugs and related products for the treatment of oncology; Bristol-Myers admits that it marketed and sold its drugs directly to medical providers both prior to and after its acquisition of OTN; Bristol-Myers and OTN admit they each employ and maintain marketing and sales departments; and Bristol-Myers admits that it has paid sales commissions to OTN.

74. Apothecon denies the allegations in Paragraph 74 of the AMCC, except Apothecon admits that it is a Delaware corporation and that it is a subsidiary of Bristol-Myers.

75. The allegations in Paragraph 75 of the AMCC state a conclusion to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraph 75 of the AMCC.

76. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 of the AMCC, except that Bristol-Myers admits that it manufactures or formerly manufactured Blenoxane®, Paraplatin®, Cytosan®, Rubex®, Etopophos®, Vepesid®, Taxol® and Fungizone®, which are covered by Medicare Part B; OTN admits that it distributes or formerly distributed these drugs; and Apothecon admits that it formerly manufactured and distributed Fungizone®.

77. BMS Group admits that the Plaintiffs purport to bring this action against BMS Group as a participant of Together Rx LLC ("Together Rx"), as described in Paragraphs 542 through 618 and 692 through 725 of the AMCC. BMS Group denies that Plaintiffs are entitled to maintain this action in the manner alleged or that Plaintiffs have pled a proper class.

78-131. The allegations in Paragraphs 78 through 131 of the AMCC are directed to other defendants and require no response from BMS Group. To the extent the allegations in Paragraphs 78 through 131 of the AMCC are deemed to include allegations against BMS Group, they are denied, except BMS Group admits that it is a participant of Together Rx, LLC, a Delaware limited liability company, as alleged in Paragraph 131 of the AMCC.

132. The allegations in Paragraph 132 of the AMCC state a legal conclusion to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraph 132 of the AMCC.

133. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 133 of the AMCC, except admits that prescription drugs are dispensed to patients by different types of medical providers, including physicians and retail pharmacies.

134. BMS Group denies the allegations in Paragraphs 134 of the AMCC, except admits that Congress and CMS have mandated that Medicare Part B reimbursements be based, in part, upon AWP, and that AWP is used outside the Medicare Part B context.

135-136. BMS Group denies the allegations in Paragraphs 135 through 136 of the AMCC, except admits that pharmaceutical industry pricing publications periodically report AWP for prescription medicines sold in the United States. BMS Group states that the 1999

edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 136 of the AMCC speak for themselves and are the best evidence of their contents.

137-141. BMS Group denies the allegations in Paragraph 137 through 141 of the AMCC.

142-144. BMS Group admits the allegations in Paragraphs 142 through 144 of the AMCC.

145. BMS Group denies the allegations in Paragraph 145 of the AMCC, except admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth in 45 C.F.R. 405.517, which is the best evidence of its contents.

146-147. BMS Group denies the allegations in Paragraphs 146 through 147 of the AMCC, except states that it is without knowledge or information sufficient to form a belief as to Medicare's "historical" use of AWP's in the "Red Book or other compendia . . . as a ceiling for . . . reimbursement;" states that 42 C.F.R. § 405.517 speaks for itself and is the best evidence of its contents; and admits that the estimated acquisition cost for a drug could be determined by the Medicare Program based on surveys.

148. BMS Group denies the allegations in Paragraph 148 of the AMCC, except admits that the Medicare Program has on occasion publicly announced that it would use some form of the AWP published in pharmaceutical industry pricing publications as a basis for reimbursement and states that Program Memo AB-99-63 cited in Paragraph 148 of the AMCC speaks for itself and is the best evidence of its contents.

149. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 149 and states that Program Memo AB-99-63 cited in Paragraph 149 of the AMCC speaks for itself and is the best evidence of its contents.

150-151. BMS Group denies knowledge or information sufficient to form a belief as to the extent to which Medicare Part B beneficiaries or the insurers actually make the co-payments, except admits the allegations in Paragraphs 150 through 151 of the AMCC.

152. BMS Group denies the allegations in Paragraph 152 of the AMCC, except admits that it sends certain pricing information to independent publishing companies and does not report AWP's directly to the federal government; admits upon information and belief that there are no government regulations describing how AWP's are calculated, nor any other statutory or regulatory definitions or descriptions of AWP's; and admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications.

153-154. BMS Group denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such is applicable to BMS Group, and states that the April 2003 OIG report cited in Paragraphs 153 through 154 of the AMCC speaks for itself and is the best evidence of its contents.

155. BMS Group denies the allegations in Paragraph 155 of the AMCC, except admits that the governmental agencies listed in Paragraph 155 of the AMCC have conducted investigations concerning pricing in the pharmaceutical industry and, to the best of BMS Group's knowledge and belief, the GAO has never conducted an investigation of BMS with respect to its pricing practices. To the extent the allegations in Paragraph 155 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations.

156-157. BMS Group denies the existence of, and its participation in, any "scheme" cited in Paragraph 156 of the AMCC. BMS Group states that the September 28, 2000 letter from

Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 156 through 157 of the AMCC speaks for itself and is the best evidence of its contents. BMS Group denies that Plaintiffs have accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to BMS Group.

158. Upon information and belief, BMS Group admits the allegations of Paragraph 158 of the AMCC.

159. BMS Group denies the allegations in Paragraph 159 of the AMCC, and specifically denies the existence of, and its participation in, any “scheme” as alleged in Paragraph 159 of the AMCC.

160. BMS denies the allegations of paragraph 160 of the AMCC as to BMS Group and states that it is without knowledge or information sufficient to form a belief as to the truth of those allegations as they pertain to other defendants.

161-184. BMS Group denies the allegations in Paragraphs 161 through 184 of the AMCC, except admits that, from time to time, it has provided free samples of certain of its drugs to medical providers in a lawful manner. To the extent the allegations in Paragraphs 161 through 184 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the March 30, 2003 Wall Street Journal article cited in Paragraph 178 of the AMCC speaks for itself and is the best evidence of its contents.

185. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 185 of the AMCC.

186-191. BMS Group denies the allegations of Paragraph 186 through 191 as they pertain to it and, to the extent the allegations in Paragraphs 186 through 191 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the *Red Book* and the unidentified DOJ report cited in Paragraph 187 of the AMCC and the pleadings cited in Paragraphs 189 through 190 of the AMCC and subparts speak for themselves and are the best evidence of their contents.

192. BMS Group denies the allegations in Paragraph 192 of the AMCC, except admits that certain price discounts it gives to customers are confidential competitive information and states the 2003 CMS document cited in Paragraph 192 of the AMCC speaks for itself and is the best evidence of its contents.

193-196. BMS Group denies the allegations in Paragraphs 193 through 196 of the AMCC.

197. BMS Group denies that Plaintiffs lacked inquiry or other notice of the issues alleged in Paragraph 197 of the AMCC. BMS Group specifically states, to the contrary, that such issues were well known before Plaintiffs elected to bring this lawsuit.

198-199. The allegations in Paragraphs 198 through 199 of the AMCC state legal conclusions to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraphs 198 through 199 of the AMCC.

200. BMS Group denies the allegations in Paragraph 200 of the AMCC that pertain to it and, to the extent the allegations in Paragraph 200 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations.

201-326. The allegations in Paragraphs 201 through 326 of the AMCC are directed to other defendants and require no response from BMS Group. To the extent allegations in Paragraphs 201 through 326 of the AMCC are deemed to include allegations against BMS Group, they are denied.

327. BMS Group denies the allegations in Paragraph 327 of the AMCC and states that specific drugs as to which Plaintiffs seek relief are selected by Plaintiffs and do not require a response from BMS Group; to the extent that such a response is required, BMS Group denies that Plaintiffs are entitled to a judgment or any relief.

328. BMS Group denies the allegations in Paragraph 328 of the AMCC, except admits that the governmental agencies listed in Paragraph 328 of the AMCC have conducted investigations concerning pricing in the pharmaceutical industry.

329. The allegations in Paragraph 329 of the AMCC state legal conclusions to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraph 329 of the AMCC and states that the February 27, 2001 letter from Representative Stark to BMS Group cited in Paragraph 329 of the AMCC speaks for itself and is the best evidence of its contents.

330. BMS Group denies the allegations in Paragraph 330 of the AMCC and states that the February 27, 2001 letter from Representative Stark to BMS Group cited in Paragraph 330 of the AMCC speaks for itself and is the best evidence of its contents.

331. BMS Group denies the allegations in Paragraph 331 of the AMCC, except admits that it communicated with industry compendia concerning certain prices of its products during the Class Period. BMS Group further states that the document written by Denise Kaszuba cited

in Paragraph 331 speaks for itself and is the best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from this document.

332. BMS Group denies the allegations in Paragraph 332 of the AMCC, except states that the BMS Group document (BMSAWP/0011246) cited in Paragraph 332 speaks for itself and is the best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from this document.

333. BMS Group denies the allegations in Paragraph 333 of the AMCC that pertain to it and, to the extent the allegations in Paragraph 333 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the BMS Group document (BMS3CA/000128) cited in Paragraph 333 of the AMCC speaks for itself and is the best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from this document.

334. BMS Group denies the allegations in Paragraph 334 of the AMCC, except admits that it was sometimes aware of and noted the AWP's of its competitors' drugs. BMS Group notes that the document number cited in Paragraph 334 of the AMCC does not contain the quoted language.

335. BMS Group denies the allegations in Paragraph 335 of the AMCC that pertain to it and states that the BMS Group document cited in Paragraph 335 of the AMCC speaks for itself and is the best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from the alleged quotation from this document.

336. BMS Group denies the allegations in Paragraph 336 of the AMCC and, to the extent the allegations in Paragraph 336 of the AMCC refer to the knowledge, conduct or actions

of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the *Red Book* and the unidentified DHHS report cited in Paragraph 336 of the AMCC speak for themselves and are the best evidence of their contents. BMS Group denies the conclusions that Plaintiffs draw from these documents.

337. BMS Group denies the allegations in Paragraph 337 of the AMCC.

338. BMS Group denies the allegations in Paragraph 338 of the AMCC and states that the quotation from the February 27, 2001 letter from Representative Stark to BMS Group cited in Paragraph 338 of the AMCC speaks for itself and is the best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from the alleged quotation from this document.

339. BMS Group denies the allegations of Paragraph 339 and states that the documents referred to in Paragraph 339 of the AMCC speak for themselves and are the best evidence of their contents. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 339 of the AMCC.

340. BMS Group denies the allegations in Paragraph 340 of the AMCC and states that the documents referred to in Paragraph 340 of the AMCC speak for themselves and are the best evidence of their contents.

341. BMS Group denies the allegations in Paragraph 341 of the AMCC.

342. BMS Group denies the allegations in Paragraph 342 of the AMCC and states that the DHHS report cited in Paragraph 342 of the AMCC speaks for itself and is the best evidence of its contents.

343. BMS Group denies the allegations in Paragraph 343 of the AMCC and states that the 2001 *Red Book* and the unidentified DOJ documents cited in Paragraph 343 of the AMCC

speak for themselves and are the best evidence of their contents. BMS Group denies the conclusion that Plaintiffs draw from these documents.

344. Bristol-Myers denies the allegations in Paragraph 344 of the AMCC, except admits that it manufactured drugs called Paraplatin®, Rubex® and Taxol®. BMS Group states that the 1997 OIG report and the revenue figures cited in Paragraph 344 of the AMCC speak for themselves and are the best evidence of their contents.

345. The allegations in Paragraph 345 of the AMCC and its subparts state a legal conclusion to which no response is required. To the extent a response is required, BMS Group denies the allegations in Paragraph 345 of the AMCC.

346. BMS Group denies the allegations in Paragraph 346 of the AMCC, except states that the BMS Group document cited in Paragraph 346 of the AMCC speaks for itself and is the best evidence of its contents.

347. BMS Group denies the allegations in Paragraph 347 of the AMCC and, to the extent the allegations in Paragraph 347 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the documents referred to in Paragraph 347 of the AMCC speak for themselves and are the best evidence of their contents. BMS Group denies the conclusion that Plaintiffs draw from these documents.

348. BMS Group denies the allegations in Paragraph 348 of the AMCC, except admits that the pharmaceutical industry pricing publications publish AWP's of its drugs. BMS Group states that the document referred to in Paragraph 348 of the AMCC speaks for itself and is the

best evidence of its contents. BMS Group denies the conclusion that Plaintiffs draw from this document.

349-540. The allegations in Paragraphs 349 through 540 of the AMCC are directed to another defendant and require no response from BMS Group. To the extent allegations in Paragraphs 349 through 540 of the AMCC are deemed to include allegations against BMS Group, they are denied.

541. BMS Group denies the allegations in Paragraph 541 of the AMCC.

542-546. BMS Group denies the allegations in Paragraphs 542 through 546 of the AMCC, except admits that it is among the first participants in Together Rx and admits that the Together Rx Card Program is designed as a prescription drug savings program.

547. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 547 of the AMCC.

548. BMS Group admits that, at the time of the AMCC, the Medicare Program generally did not cover the cost of self-administered prescription medicines and that Congress has debated the issue of prescription medicine coverage under the Medicare Program. BMS Group is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 548 of the AMCC.

549. BMS Group admits that Congress has examined the pricing of prescription medicines in the United States and has considered amending the Medicare and Medicaid prescription medicine programs. To the extent the allegations in Paragraph 549 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than BMS Group, BMS Group is without knowledge or information sufficient to form a belief as to the truth of those allegations. BMS Group states that the April 4, 2001 Prescription Drug Fairness for Seniors Act